

92



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,705	07/26/2001	Brad T. Bosworth	21419/91512	2430
23644	7590	07/23/2004	<div>EXAMINER</div> <div>WOITACH, JOSEPH T</div>	
BARNES & THORNBURG P.O. BOX 2786 CHICAGO, IL 60690-2786			<div>ART UNIT</div> <div>1632</div>	<div>PAPER NUMBER</div>

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/844,705

Applicant(s)

BOSWORTH ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

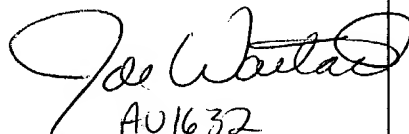
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 3-6.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
AU1632

Continuation of 2. NOTE: The proposed amendments to encompass carbohydrate structures generated by FUT1 requires a new search and consideration. In addition, it raises issues of new matter because while the mutation at the allele is associated with a particular phenotype, there is no evidence that the allele results in a change of carbohydrate structures or functional differences in the FUT1 enzyme activity that results in a change in a difference in detectable carbohydrates. Even if the difference in amino acid sequence of FUT1 results in a difference in enzyme activity, there is no support to what that change is or support that this is what results in the resistance to E. coli F18 colonization. The specification supports generally that the allele is associated with resistance to F18, however there is no nexus that the phenotype is a direct consequence of the allele and not some other gene at that loci or tightly associated with the allele.

Continuation of 3. Applicant's reply has overcome the following rejection(s): the terminal disclaimer filed 6/23/2004 has obviated the obvious double patenting rejection.

Continuation of 5. does NOT place the application in condition for allowance because: To the extent that Applicants' arguments apply to the instant claims, it is maintained that without a clear nexus between the gene product and the phenotype, it would require empirical analysis and further characterization to establish the specific cause and/or consequence of the observed phenotype and whether it could be extended to other E. coli. Again, it is noted that the exact mechanism of colonization and the reason why the allele is associated with resistance is not known, and the art of record supports that such observations represent only a correlative linkage with what was tested, and such observation would not necessarily be extended beyond the observation.